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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/856,859	BATTERSBY ET AL.	
	Examiner	Art Unit	
	TERESA WESSENDORF	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,18-29,63,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15, 18-29, 63 and 65-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 15, 18-29, 63 and 65-66 are pending and under examination in the application.

Withdrawn Rejection

In view of the amendments to the claims and applicants'' arguments the 35 USC 102 rejection over Yamashita is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 18-29, 63 and 65-66, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 15 is vague and indefinite as to the metes and bounds of the claimed "features" that detectably varies among a plurality of individual carriers within the population of

carriers. It is not clear as to what is included or precluded by said features or in what respect the features varies so as to be detected by any means or from one another.

2. Claim 15 is vague and indefinite as to "all the features that define a corresponding code" i.e., in what aspects or manner a code corresponds to all the features of a carrier. Also, the metes and bounds of "all" the features of a carrier of even a single carrier are vague and indefinite.

3. Claims 19, 23, 26, 63, 65 and 66 are vague and indefinite in the recitation of “one or more”. “More” would cover an infinite amount or number. "At least" is better.

4. Claim 19 is vague and indefinite as to the illumination of the carrier with “selected **vectors**”.

5. Claim 65(which indirectly depends on claim 15) is inconsistent with the base claim 15. The base claim recites the negative limitation as of the features of the carrier not being based on shape. Claim 65 recites said features as shape.

6. Claim 15 is vague and indefinites. It is unclear whether the code that distinctively identifies a carrier before, during and after a combinatorial synthesis from other carriers is different in each stages of the combinatorial synthesis.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

I. Claims 15, 18-19, 21 and 29, as amended, are rejected under 35 U.S.C. 102 (b) as being anticipated by Egner et al (Chem. Commun., 1997)for reasons of record as reiterated below.

Egner discloses at e.g., page 735, col. 1, a covalently dye beads for combinatorial synthesis of compounds tagged with fluorescence. The dye (claim 21) was covalently coupled by amide bond (claim 29) to Tentagel S-NH2 beads (130 um, reads on claim 28 of about 50um). The fluorescence technique was extended by the use of a laser system (light emanating of claim 1). The Tentagel beads were labeled with florescein and erythrosin. See also Fig. 1 and Fig. 2. and Fig. 4 at page 736. Egner discloses at page 736, col. 2; that the use of colored and fluorescent beads has the potential to simplify the identification of library members for single bead screening application. Please

see also the footnotes which teach the excitation of fluorescence by laser beam (claim 19).

Accordingly, the specific carrier of Egner fully meets the broad claimed plurality of carriers with at least two detectable features.

Response to Arguments

Applicants argue that the mere fact that there is Raman scattering from a bead of Egner is not indicative that Egner discloses a bead having a "light scattering feature" as recited in the instant claims. The "light scattering feature" of the instant claims must, in combination with at least one other feature, define the corresponding distinctive code for its respective carrier. The Examiner has pointed to a general statement about Raman scattering from a bead defining the lower limit of detection of the fluorescent dye used to label the beads of Egner. Enger does not, however, teach that the Raman scattering observed was or could be used in combination with molecular fluorescence as a second "feature" defining a distinctive code. In fact, Egner does not teach or even suggest that Raman scattering provides any useful means of distinguishing one bead from another. As such, the Raman

scattering disclosed by Egner does not have the properties required by the "light scattering feature" of the claims.

In reply, attention is drawn again to Egner's teachings at e.g., page 735, paragraph bridging col. 1 and col. 2, which teaches the combination of fluorescence and Raman(light scattering) features as claimed:

> Labeling down …….the limits were determined by the amount of background fluorescence **and** Raman scattering (i.e., light scattering as claim) from the bead.

Furthermore, Egner teaches at e.g., page 736, col. 1:

> ……[S]everal different dyes with varying **absorbance/emission spectra** and varying the dye loadings (by orders of magnitude)……. 9 coloured and fluorescent beads have the potential to simplify the identification of library members for single bead screening applications.

Egner further teaches at e.g., page 736 col. 2 the fluorescence of the different dyes and light dispersed with a scanning monochromator and detected with a photomultiplier. Fig. 1 at page 735 further provide the other features of the beads.

Thus, Egner teaches the combined fluorescence and light scattering, as claimed, to identify each of the members of a

library on bead. This would meet applicants' coined term "features" of the carrier. (Please note the broad definition of the features in the specification at e.g., page 14, lines 20. By "features integrally associated with the carrier" or "features integrally associated therewith" is meant features of the carrier and/or features of one or more elements, molecules, groups, tags and the like attached to the carrier.)

II. Claims 15 and 18-21, as amended, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Seul et al (USP 7083914) for reasons of record repeated below.

(Please note that the rejections and/or responses of the last Office action have been amended to address the present amendments to the claims and applicants' response.)

Seul et al discloses throughout the patent at e.g., col. 5, line 29 up to col. 6, line 56:

> …[c]olor codes for the purpose of uniquely labeling members of a group of beads or equivalent objects ("beads") to preserve the chemical identity of the beads and thus the identity of bead-coupled chemical compounds. These color codes are based on a set of encoding fluorophores of distinguishable wavelengths, excited-state lifetimes and levels of intensity, the latter controlled by adjusting the abundances of dyes.

> Binary and extended binary color codes offer large coding capacity and represent a general strategy to encode multi-step reaction histories such as those encountered in divide-couple-recombine (DCR) synthesis strategies for combinatorial chemical libraries.
>
> Simple and extended simple color codes offer an efficient strategy to encode a smaller set of distinct chemistries that are typical of panels displaying multiple targets or probes in biochemical assays including multi-agent diagnostic and environmental tests and other biochemical assays.
>
> All color codes can be augmented by varying distinguishable features of beads such as shape and size or other suitable physico-chemical parameter associated with bead cores such as polarizability.
> Please see also all the drawing Figures.

Accordingly, the specific carrier of Seul et al fully meets the broad claimed plurality of carriers with at least two detectable features.

Response to Arguments

Applicants state that the particles of Seul are tagged combinatorial synthesis. See, e.g., Seul at column 6, lines 47-54, which states: Implementation of Color Codes:

> The color coding strategy of the present invention provides a method to place a set of fluorophores---or, more generally, chromophores-on each bead so as to uniquely encode the chemical identity of the compound on that bead. Specifically, **during each coupling step in the course of DCR combinatorial synthesis, one or more fluorophores are attached to each bead.** (column 6, lines 47-54, emphasis added)

> Seul does not teach or suggest use of the beads that are coded prior to combinatorial synthesis. Rather, the Seul teaches that, for combinatorial synthesis application, coding occurs during synthesis. While not acquiescing that Seul teaches the other elements of Claim 15, Applicants respectfully point out that the beads of Seul do not comprise codes that distinctively identify the carrier before, during, and after a combinatorial synthesis.

In reply, the patentability of a product does not depend on its method of production or use. If the product in the product-by-process (or use) claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made (or can be used) by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). See also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971). MPEP § 2112.01.

The claimed coding before combinatorial synthesis would have been inherent to the combinatorial synthesis of Seul since

the same coded carrier is produced during and after combinatorial synthesis. Furthermore, the above-cited passage of Seul relates to a strategy i.e., method of coding not to the compound per se. It would be within the ordinary skill in the art at the time of applicants' invention to place the code prior, during and after combinatorial synthesis(if not already inherently done by Seul). The same product i.e., a uniquely coded carrier is obtained by Seul as the claimed coded carriers.

IV. Claims 15, 18-29, 63 and 65-66, as amended, are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kauvar et al (USP 6642062) (as evidenced by Tao Jia-ping et al(Chinese Journal of Physical Medicine (Vol. 17(3), September 1995, p 168-171) and by applicants' disclosure of known prior art) for reasons set forth in the previous office action and reiterated below.

(Please note that the rejections and/or responses of the last Office action have been amended to address the present amendments to the claims and applicants' response.)

Kauvar discloses throughout the patent at e.g., col. 2, line 48 up to col. 5, lines 63:

> …[a] **label which comprises a particulate support to which is bound at least two signal generating moieties, which moieties generate signals that can be distinguished in situ, such as light of different wavelengths.** These labels are distinguishable by any instrumentation which contains separate means for detection for each of the at least two in situ signals generated.
>
> …. [a] collection of labels wherein the ratio of the moieties differs from label to label in the collection. Typically, this collection of labels provides identifiable members that number at least twenty…. Thus, if the reliability of detection of each color is plus or minus 10 percent, 10 gray labels exist for each signal and therefore 100 hues can be distinguished when **two signal generating moieties are included in each label.**
> This instrumentation provides **fluorescence excitation and capacity for detection of three separate wavelengths of light**……Such beads are available commercially in several different colors of fluorophores with high uniformity in size and fluorophore doping levels from Flow Cytometry Standards Corp…..among others.
>
> ….[t]he number of reagents that can be separately detected under these conditions by systematic and precise doping of particulate supports with signal generating moieties, typically fluorophores, of different colors corresponding to the CCD detectors employed, at specified ratios. Particles with different ratios of the fluorophores generate different detection signals in this system. Because the ratios of the fluorophores can be varied at will, up to a point where a forced proximity of the dyes leads to quenching, many different "hues" can be generated in a collection of labeled particles, each particle type having a unique ratio and/or amount of color generating moieties.
>
> As used herein, the term "label" is generally used to describe a particulate support to which has been bound an appropriate array of signal generating moieties. The signal-generating moieties must be such that the signals

are detected in situ on the particulate support. Thus, it is unnecessary to detach the signal-generating moieties from the support in order to ascertain their ratio. Their ratio is read directly by means of the "hue" of the label. Color is a preferred signal. **The labels…..contain at least two, and preferably at least three, distinguishable signal generating moieties.**

As visible light is a particularly convenient way to generate a particular "hue,"… However, other signal generating moieties can be employed or an indirect method to generate visible light may be used. In addition, heavy atom clusters of different materials, **for example colloidal gold dots**(reads on e.g., claim 22) **versus ferrite rods offer different scattering characteristics with respect to electron microscope beams.** The preferred "color generating" moieties are typically fluorophores, but they can also generate a characteristic wavelength either by reflectance (simple dyes) or by emission (fluorophores or de novo light-generating compounds such as a luciferase or other chemiluminescent system). A number of chemiluminescent systems are known in the art such as horseradish peroxidase-based generation of chemiluminescent products…. In addition to fluorescent dyes, phosphorescent materials (reads on claim 18) may also be employed which adds the advantage that time resolved fluorescence distinguishes signals that would be equivalent averaged over a longer detection period.

The supporting particles are typically 0.1-1 .mu.m in diameter and are preferably latex. However, smaller particles may also be used. Generally, 50 nm (0.05 .mu.m) is considered an approximate minimum; it has been possible in some contexts to use particles as large as 5 .mu.m, although this is not preferred.(Reads on claim 28). The use of larger particles results in lower diffusion rates and thus, effectively, less efficient and less vivid labeling. A preferred range is 100-500, preferably 100-300, and more preferably 100-200 nm diameter particles. The particulate supports are generally spherical, (reads on claim 65) and the microscopic techniques employed can distinguish spherical shapes from other general outlines. **Silica** gel particles may also be used. (reads on claims 26 and 27). Any particulate that has suitable physical properties (does not spontaneously aggregate, adhere, or otherwise fail to

behave as an independent particle) and which can be suitably derivatized with the color generating moieties and with the test reagent may be used.

The construction of the particle itself affects the hue detected. In addition to differences attributed to the size of the particle, (reads on claim 25) as indicated above, the shape will determine the nature of the signal. Shapes can vary along the continuum of sphere to oval to rod to string, for example. Star shapes or other arbitrarily shaped particles can be created by x-ray lithography so as to have a distinctive point spread function. (Reads on claim 65.)

Accordingly, the specific carrier of Kauvar fully meets the claimed plurality of carriers with at least two detectable features.

Response to Arguments

Applicants recognize that Kauvar discloses using combinations of dyes, particularly fluorescent dyes, to generate multihued labels. But argue that Kauver does not teach the use of the multihued beads as a carrier for combinatorial synthesis. Rather, for combinatorial library screening, Kauvar teaches that the addition of color generating moieties..."can be carried out in conjunction with the synthesis of the library members"...' (col. 9, line 35). That is, Kauver teaches encoding the particles during the combinatorial synthesis. Applicants recognize that, even though Kauvar suggests coding during

combinatorial synthesis, however argue that there is no disclosure of how to accomplish such coding. Kauver et al. do not teach or suggest a plurality of carriers comprising a population of detectably distinct carriers ... each carrier having a code which distinctively identifies a respective carrier before, during and after a combinatorial synthesis from other carriers. The teachings of Jai-ping are discussed above. As previously noted, the capabilities of multiparameter flow cytometry as disclosed by Jai-ping do not confer features on the beads of Kauvar. Neither Kauver nor Jai-ping teach or suggest that the beads of Kauver are, or could be distinctively identified before, during and after combinatorial synthesis, as required by the instant claims.

In reply, attention is drawn again to Kauvar's disclosure above which states, for example:

> This instrumentation provides fluorescence excitation and capacity for detection of three separate wavelengths of light……Such beads are available commercially in several different colors of fluorophores with high uniformity in size and fluorophore doping levels from Flow Cytometry Standards Corp…..(as evident from applicants' disclosure or Jia-ping of the known property of flow cytometry.)

Furthermore, the patentability of a product does not depend on its method of production or use. If the product in the product-by-process (or use) claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made (or used) by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). See also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971). MPEP § 2112.01.

The claimed coding before combinatorial synthesis would have been inherent to the combinatorial synthesis of Kauvar since the same coded carrier is produced during and after combinatorial synthesis. It would be within the ordinary skill in the art at the time of applicants' invention to place the code prior, during and after combinatorial synthesis in the coding strategy of Kauvar. The same product i.e., a uniquely coded carrier is obtained by Kauvar as that claimed even when the coding was done during combinatorial synthesis. Applicants have not shown that the placing of coding before, during and after combinatorial results in a different product of coded carriers.

Claim Rejections - 35 USC § 103

IV. Claims 15, 18-29, 63 and 65-66, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Egner et al or Kauvar or Seul in view of Yamashita(WO 95/32425) and either Kris et al (USP 6238869) or Kimura et al (USP 6228480).

Each of Egner, Kauvar and Seul is discussed above. Each of these references does not disclose the carrier as a silica microparticle as recited in e.g., claim 27 and the coding strategy before and after combinatorial synthesis

Kris discloses throughout the patent at e.g., col. 5, lines 3-30:

> The surface (usually a solid) can be any of a variety of organic or inorganic materials or combinations thereof, including,…plastics such as polypropylene or polystyrene; ceramic; silicon; (fused) silica, quartz or glass microscope slide or a glass cover slip;..Substrates that are transparent to light are useful when the method of performing an assay involves optical detection….The shape of the surface is not critical. It can, for example, be a flat surface such as a square, rectangle, or circle; a curved surface; or a three dimensional surface such as a bead, particle, strand, precipitate, tube, sphere; etc.

Kimura et al discloses at e.g., col. 4, lines 15-45:

> If the adhesive layer is composed of a resin that contains colloidal silica, it is preferable if the diameter of colloidal silica particles is 10 nm or less……As a method to

> introduce such colloidal silica into the resin, it is known that a method to mix a resin solution with a colloidal silica solution, then apply it and subsequently dry it to form an adhesive layer is the easiest, however, a method to form an adhesive layer by allowing a resin to polymerization while dispersing colloidal silica in the resin and then to apply the synthesized resin and dry it, is also acceptable. It is also possible to use colloidal silica after treating it with a silane coupler for improving adhesive property and dispersibity of colloidal silica and a resin.
>
> As examples for a resin whereto colloidal silica is introduced, acryl resin, acryl-silicon resin, epoxy-silicon resin, silicon-modified resin, urethane resin, epoxy resin, polyester resin, alkyd resin, etc. are given, however, silicon-modified resins including acryl-silicon resin and epoxy-silicon resin, are the most suitable one in term of durability.
> As the colloidal silica, any silica sol, which is produced either by subjecting sodium silicate solution to cation exchange or by subjecting silicon alkoxide to hydrolysis, can be used.

Yamashita discloses that prior to encoding a synthetic step in each library, a sorting procedure is performed in which a group of similarly tagged beads is sorted into a number of containers corresponding to the number of different choices of building block or "synthon" for the synthetic step. The combinatorial libraries thus prepared will contain tagged beads that identify the reaction sequence of a single synthetic step (see page 15, lines 29- 32).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use silica microparticle as the carrier in anyone of the primary references as taught by either Kris or Kimura. One would have a reasonable expectation or predictable result since as Kimura or Kris teaches silica or a large number of carriers has been successfully employed in the art for combinatorial library synthesis of compounds. Furthermore, it would have been obvious to code a carrier prior to the combinatorial synthesis of a compound in the method of Kauvar or Seul or Egner as taught by Yamashita. One would have a reasonable expectation of success in coding the carrier of Kauvar or Seul or Egner prior to synthesis as this would identify or confirm uniquely the code during and after synthesis.

Response to Arguments

Applicants state that the teachings of Egner, Kauver and Seul are discussed above. For the reasons recited above, Applicants submit that none of these references teach or suggest each of the elements of the instant claims. Kris discloses the properties of certain solids. Kimura discloses the properties of

certain adhesive layers and solids. Kris and Kimura fail to cure the deficiencies of Egner, Seul and Kauvar.

In reply, the responses above under Egner, Kauver and Seul are incorporated here as applicants have simply done. Kris and Kimura are employed for the disclosure of the advantages in the use of silica microparticle that provides the motivation to use said silica microparticle carrier. Thus, the combined teachings of the prior art render obvious the claimed plurality of carriers.

When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." KSR International Co. v. Teleflex Inc., 550 USPQ2d 1385 (2007).

There is nothing new and unobvious in the claim plurality of carrier for combinatorial library synthesis wherein the multitude of carriers is coded to identify or differentiate one from the other. Coding a multitude of carrier in a library which contains millions of compounds obviously facilitates identification of the synthesized compounds in the carrier.

No claim is allowed.

[It is suggested that the claims be drafted to recite a method of using or making that would differentiate from the method of the art and might make a claim allowable.]

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA WESSENDORF whose telephone number is (571)272-0812. The examiner can normally be reached on flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TERESA WESSENDORF/

Primary Examiner, Art Unit 1639